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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/768,816	01/23/2001	Suzy Charbit	H7708-002	1320

7590

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I.P. Docketing
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EXAMINER

BAHAR, MOJDEH

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 05/07/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/768,816

Applicant(s)

CHARBIT ET AL.

Examiner

Mojdeh Bahar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 15-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's response to the first office action July 31, 2001, submitted January 23, 2002 (Paper No. 9) is acknowledged. Applicant's remarks are persuasive to remove the rejection under 35 USC 102 in the previous office action.

Newly submitted claims 15-23 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: these claims require the employment of two different groups of actives, whereas the original claims 1-14 require the employment of only a single pharmaceutical active. The newly presented claims 15-23 have a different mode of operation than the originally submitted claims.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 15-23 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1-14 are herein examined on the merits.

Objections

The amendment filed April 18, 2001 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "pulmonary fibrosis".

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. "Pulmonary fibrosis" is not specifically described in the specification.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 09/663528. Although the conflicting claims are not identical, they are not patentably distinct from each other because end stage osteoarthritis is an inflammatory disease.

Claims 1-14 of the instant application are drawn to a method of treating inflammatory and autoimmune diseases employing diacerhein. End stage osteoarthritis is an inflammatory disease. Both sets of claims are directed to treating inflammatory diseases using the same active, and are therefore obvious variants of each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martel-Pelletier et al. in view of Marcolongo et al. and applicant's admissions on page 1 of the specification.

Martel-Pelletier et al. discloses a method of treating osteo-arthritis (OA) employing diacerhein and its active metabolite rhein both of which are known to inhibit IL-1 beta synthesis and consequently have a beneficial affect on OA, see particularly abstract and page 754 col.1.

Martel-Pelletier et al. does not teach the amount of diacerhein to be administered or the dosage form, neither does it teach the treatment of other inflammatory or autoimmune diseases.

Marcolongo et al. teaches a method of treating osteo-arthritis comprising administering 50 mg of diacerhein per day in tablet form.

On page one of the specification applicant enumerates some pathological conditions characterized by an increases IL-1 and/or TNF-alpha level: rheumatoid arthritis, psoriatic arthritis, Wegener's disease, etc., see page 1 of the specification.

It would have been obvious to one of ordinary skill at the time the invention was made to administer the amounts of diacerhein taught in Marcolongo et al. in Martel-Pelletier et al.'s method of treating osteoarthritis and to employ a capsule as the dosage form for the composition. It would have also been obvious to employ diacerhein in a method of treating rheumatoid arthritis, psoriatic arthritis, Wegener's disease, etc.

One of ordinary skill in the art would have been motivated to employ the amount of diacerhein taught in Marcolongo et al. in Martel-Pelletier et al.'s method of treating osteoarthritis because this amount is known to be useful in a method of treating osteo-arthritis, an inflammatory disease. Moreover the administration of a known active in a known dosage form, i.e. capsule is within the purview of the skilled artisan. Furthermore one of ordinary skill in the art would have been motivated to employ diacerhein, which is known to inhibit the synthesis of IL-1 beta, in a method of treating diseases characterized by an increases IL-1 and/or TNF-alpha level: rheumatoid arthritis, psoriatic arthritis, Wegener's disease, etc., and reasonably expect similar therapeutic effects.

Response to Arguments

Applicant's arguments filed January 23, 2002 regarding rejection of claim 3 under 35 USC 112 and the objection to the specification have been fully considered but they are not persuasive. Note that the original disclosure did not teach/claim the particular disorder of "pulmonary fibrosis." Moreover, the etiology of this disease is unknown, hence the name idiopathic pulmonary fibrosis. The term idiopathic means, a peculiar illness, of unknown cause, see Pulmonary Fibrosis Foundation reference enclosed herewith. Note also that the claims recite "method of treating an underlying cause of a pathological condition". Given that the underlying cause of pulmonary fibrosis is uncertain at best, "pulmonary fibrosis" is not supported by the original disclosure.

Applicant's arguments filed January 23, 2002 regarding rejection of claim 1-14 under judicially created doctrine of obviousness double patenting have been fully considered but they are not persuasive. The claims of Application No. 09/663528 are drawn to method of treating osteoarthritis, a well-known end stage inflammatory disease. The instant claims are drawn to treating inflammatory diseases which encompass OA. Therefore the obviousness double patenting rejection is appropriate.

Applicant's arguments filed January 23, 2002 regarding rejection under 35 USC 103 have been fully considered but they are not persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Note that as set forth in the previous action Martel-Pelletier et al. discloses a

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method of treating osteo-arthritis (OA) employing diacerhein and its active metabolite rhein both of which are known to inhibit IL-1 beta synthesis and consequently have a beneficial affect on OA. The applicant enumerates several diseases that are known to be characterized by increased IL-1 levels. It would follow that the Skilled artisan would use diacerhein and its active metabolite rhein, both of which known to inhibit IL-1 beta synthesis to treat the enumerated diseases on page 1 of the specification. Also note that if the Skilled Artisan administers either diacerhein or its active metabolite rhein, to a patient suffering from any of the diseases known to be characterized by increased IL-1 and or TNF-alpha they have met the claimed method steps herein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from Monday to Friday from 9:00 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
May 1, 2002

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200